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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
ASHEN, JON BENJAMIN

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 03/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,571	KASID ET AL.	
	Examiner	Art Unit	
	Jon B. Ashen	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, drawn to an isolated nucleic acid molecule, vector and cells comprising a polynucleotide selected from the group a), b), and c), as set forth in Claim 1, classified in class 536, subclass 23.1.

II. Claims 13-18, drawn to an isolated polypeptide of about 188 amino acids and specified variants and fragments thereof, classifiable in class 530, subclass 350+.

III. Claims 18-20, drawn to an antibody that binds an isolated polypeptide of about 188 amino acids as specified in claim 15, classifiable in class 530, subclass 387.9.

IV. Claims 22, 25, 27, 28 and 32, drawn to a method of inhibiting apoptosis or proliferation of a cancer cell comprising inhibiting expression of SCC-S2 using an antisense oligonucleotide, classified in class 514, subclass 44.

V. Claims 23 and 24, drawn to an antisense oligonucleotide, classified in class 536, subclass 24.5.

VI. Claims 25, 27, 28 and 32, drawn to a method of inhibiting apoptosis or proliferation of a cancer cell comprising inhibiting expression of SCC-S2 using a ribozyme, classified in class 514, subclass 44.

VII. Claims 25, 27, 28 and 32, drawn to a method of inhibiting apoptosis or proliferation of a cancer cell comprising inhibiting expression of SCC-S2 using an siRNA, classified in class 514, subclass 44.

VIII. Claims 25-27, 28 and 32, drawn to a method of inhibiting apoptosis or proliferation of a cancer cell comprising inhibiting expression of SCC-S2 using an antibody, classifiable in class 424, subclass 130.1+.

IX. Claim 30, drawn to a method of detecting cancer comprising detecting levels of SCC-S2 expression using a cDNA that hybridizes SCC-S2 and mRNA, classified in class 435, subclass 6.

X. Claim 31, drawn to a method of detecting cancer comprising detecting levels of SCC-S2 expression using an antibody that specifically binds SCC-S2, classified in class 435, subclass 7.1.

XI. Claims 33-35 and 37-39, drawn to a method for identifying small molecule inhibitors of SCC-S2, classifiable in class 436, subclass 501.

XII. Claims 36 and 40-42, drawn to a method for inhibiting cancer cell proliferation comprising administering to a patient a compound identified by the method of group XI, classifiable in class 514, subclass 1.

2. Claim 21 link(s) inventions VII, IX, X and XI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 21. Claim 29 link(s) inventions IX and X. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 29. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I, II, III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different functions. Invention I is a nucleic acid and functions to encode a polypeptide. Invention II is a polypeptide and functions as a protein to interact with other cellular constituents. Invention III is an antibody and functions to bind to a specific antigenic site on a specific protein. Invention V is an antisense nucleic acid and functions to modulate gene expression at the transcriptional or translational level.

Furthermore, searching any of Inventions I, II, III or V together would impose a serious search burden. In the instant case, prior art searches of coding nucleic acids, proteins, antibodies and antisense nucleic acids are not coextensive. Search of each of these inventions would require different key word searches in divergent patent and non-patent literature databases, including different nucleotide sequence or amino acid sequence databases. Each search would then require subsequent in-depth analysis of all relevant prior art literature and sequences, placing an undue and serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform search and examination of any of Inventions I, II, III or V together

4. Inventions III and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product that is Invention III, which is an antibody, can be used in a materially different process of using that product, such as an immunoassay to detect levels of SCC-S2 expression.

Furthermore, searching Inventions III and VIII together would impose a serious search burden. In the instant case, prior art searches of methods of inhibiting the expression of a protein are not coextensive with prior art searches of antibodies. Search of each of these inventions would require different key word searches for the compound and of the distinctive steps required by the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious and undue burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of Inventions III and VIII together.

5. Inventions V and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product that

is Invention III, which is an antisense oligonucleotide, can be used in a materially different process of using that product, such as a hybridization assay to detect cell or tissue specific gene expression of SCC-S2.

Furthermore, searching Inventions V and IV together would impose a serious search burden. In the instant case, prior art searches of methods of inhibiting the expression of a protein are not coextensive with prior art searches of antisense nucleotide sequences. Search of each of these inventions would require different key word searches of the compound and of the distinctive steps required by the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious and undue burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of Inventions V and IV together.

6. Inventions I and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product that is Invention I, which is a nucleic acid molecule encoding SCC-S2, can be used in a materially different process of using that product, such as a method of making a recombinant polypeptide.

Furthermore, searching Inventions I and IX together would impose a serious search burden. In the instant case, prior art searches of a nucleic acid molecule and a method of detecting gene expression are not coextensive. Search of each of these inventions would require a different key word and sequence search of the compound and a key word search of the distinctive steps required by the method using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious and undue burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of Inventions I and IX together.

7. Inventions III and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product that is Invention III, which is an antibody, can be used in a materially different process of using that product, such as a method of inhibiting the activity of SCC-S2 by binding.

Furthermore, searching Inventions III and X together would impose a serious search burden. In the instant case, prior art searches of an antibody and a method of detecting gene expression are not coextensive. Search of each of these inventions would require different key word searches of the compound of the distinctive steps required by the method using divergent patent and non-patent literature databases.

The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious and undue burden on the Office in terms of both search and examination. As such, it would be burdensome to perform examination of Inventions III and X together.

8. Inventions I and Inventions IV, VI-VIII and X-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and all have different functions and modes of operation. Invention I functions to encode a polypeptide and operates by translation of a nucleotide sequence. Inventions IV, VI-VIII and XII function as methods of treatment, each operating by a different mechanism to inhibit gene expression of SCC-S2. Inventions IX and X function as methods of diagnosis and each operates by different mechanisms to detect levels of SCC-S2 transcription or translation. Invention XI functions to identify small molecule inhibitors of SCC-S2 and operates by testing *in vitro* inhibitory activity of undetermined compounds.

Furthermore, searching any of Inventions I and Inventions IV, VI-VIII and X-XII together would impose a serious search burden. In the instant case, prior art searches of the nucleic acid composition and of each method are not coextensive. Search of each of these inventions would require different key word searches in divergent patent and non-patent literature databases and would require, at least, a search for particular

nucleotide sequences required for Invention I and particular steps required by each method (Inventions IV, VI-VIII and X-XII) that would not be required by each composition. Each search would then require subsequent in-depth analysis of all relevant and unrelated prior art literature, placing an undue and serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform search and examination of any of Inventions I and Inventions IV, VI-VIII and X-XII together.

9. Inventions II and Inventions IV, VI-X and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and all have different functions and modes of operation. Invention II functions to as a polypeptide, to interact with other cellular constituents and operates based on secondary and tertiary structural considerations that are related to primary amino acid sequence. Inventions IV, VI-VIII and XII function as methods of treatment, each operating by a different mechanism to inhibit gene expression of SCC-S2. Invention IX functions as methods of diagnosis and operates to detect levels of SCC-S2 transcription.

Furthermore, searching Invention II with any of Inventions IV, VI-X and XII together would impose a serious search burden. In the instant case, prior art searches of the polypeptide and of each method are not coextensive. Search of each of these

inventions would require different key word searches in divergent patent and non-patent literature databases and would require, at least, a search for amino acid sequences required by the polypeptide not required by the methods and of particular steps required by each method (Inventions IV, VI-X and XII) that would not be required for the polypeptide. Each search would then require subsequent in-depth analysis of all relevant and unrelated prior art literature, placing an undue and serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform search and examination of any of Inventions II and Inventions IV, VI-X and XII together.

10. Inventions III and Inventions IV, VI-VII, IX and XI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and all have different functions and modes of operation. Invention III functions to as an antibody to recognize a particular antigenic site and operates by binding specifically to that site. Inventions IV, VI-VII and XII function as methods of treatment, each operating by a different mechanism to inhibit gene expression of SCC-S2. Invention IX functions as methods of diagnosis and operates to detect levels of SCC-S2 transcription. Invention XI functions to identify small molecule inhibitors of SCC-S2 and operates by testing *in vitro* inhibitory activity of undetermined compounds.

Furthermore, searching Invention III with any of Inventions IV, VI-VII, IX and XI-XII together would impose a serious search burden. In the instant case, prior art searches of the antibody and of each method are not coextensive. Search of each of these inventions would require different key word searches in divergent patent and non-patent literature databases and would require, at least, a search for particular steps required by each method (Inventions IV, VI-VII, IX and XI-XII) that would not be required for the antibody. Each search would then require subsequent in-depth analysis of all relevant and unrelated prior art literature, placing an undue and serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform search and examination of Invention III with any of Inventions IV, VI-VII, IX and XI-XII together.

11. Inventions V and Inventions VI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and all have different modes of operation. Invention V, an antisense oligonucleotide, operates by a mechanism that recruits RNase H. Invention VI operates by the mechanism of direct cleavage of an mRNA transcript by a ribozyme. Invention VII operates by the mechanism of recruiting a DICER enzyme complex to ablate mRNA. Invention VIII operates by antibody binding. Invention IX operates by nucleic acid hybridization and does not modulate nucleic acid expression in any fashion.

Invention X operates by antibody binding. Invention XI operates by testing *in vitro* inhibitory activity of undetermined compounds and Invention XII operates by an unknown mechanism because it is drawn to unknown compounds.

Furthermore, searching Invention V with any of Inventions VI-XII together would impose a serious search burden. In the instant case, prior art searches of the antisense oligonucleotide and of each method are not coextensive. Search of each of these inventions would require different key word searches in divergent patent and non-patent literature databases and would require, at least, a search for particular nucleotide sequences required for the antisense oligonucleotide not required for the methods and a search for particular steps required by each method that would not be required for the antisense oligonucleotide. Each search would then require subsequent in-depth analysis of all relevant and unrelated prior art literature, placing an undue and serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform search and examination of Invention V with any of Inventions VI-XII together.

12. Inventions IV and VI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation. Each of the methods that are inventions IV, VI and VII operates by a different mechanism. Invention IV operates by a

mechanism that recruits RNase H following antisense oligonucleotide binding to an mRNA target. Invention VI operates by the mechanism of direct cleavage of an mRNA transcript based on the binding of the targeting arms of a ribozyme. Invention VII operates by the mechanism of recruiting a DICER enzyme complex to ablate a target mRNA. Furthermore, practice of each of these methods (IV, VI or VI) requires design and construction of particular antisense oligonucleotides, ribozymes or siRNAs, the process of which requires different considerations in regards to target design and synthesis of the particular antisense oligonucleotide, ribozyme or siRNA required to practice the method. Invention VIII operates by antibody binding. Invention IX operates by nucleic acid hybridization and does not modulate nucleic acid expression in any fashion. Invention X operates by antibody binding. Invention XI operates by testing *in vitro* inhibitory activity of undetermined compounds and Invention XII operates by an unknown mechanism because it is drawn to unknown compounds.

Furthermore, searching any of Inventions IV and VI-XII together would impose a serious search burden. In the instant case, prior art searches of each method are not coextensive. Search of each of these inventions would require different key word searches in divergent patent and non-patent literature databases and would require, at least, different searches for the particular method steps required to practice each claimed method. Each search would then require subsequent in-depth analysis of all relevant and unrelated prior art literature, placing an undue and serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform search and examination of any of Inventions IV and VI-XII together.

13. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and would require divergent searches of sequence and literature databases placing an undue administrative burden on the examiner, restriction for examination purposes as indicated is proper.

14. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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